IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES, LTD, AND SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 05-197 GMS **REDACTED – PUBLIC VERSION**

DEFENDANT TEVA PHARMACEUTICALS' BRIEF IN SUPPORT OF MOTION FOR LEAVE TO AMEND ITS ANSWER, DEFENSES, AND COUNTERCLAIMS

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Defendant Teva Pharmaceuticals USA, Inc. ("Teva") moves, pursuant to Federal Rule of Civil Procedure 15(a), for leave to amend its Answer, Defenses, and Counterclaims to Plaintiffs' assertion that Teva has infringed U.S. Patent No. 4,452,808 ("the 808 patent") and U.S. Patent No. 4,824,860 ("the 860 patent"). By this motion, Teva seeks to amend its Answer, Defenses, and Counterclaims to add affirmative defenses and declaratory judgment counterclaims stemming from Plaintiffs' inequitable conduct, recently made apparent during discovery. Recent discovery—

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demonstrates that each of the patents-in-suit was procured by inequitable conduct. As a result, these patents are unenforceable.

Teva manifestly satisfies the requirements for obtaining leave to amend. Teva has not unduly delayed seeking amendment; rather, it only recently completed these depositions of Plaintiffs' witnesses and received Plaintiffs' representation concerning patent prosecution, thereby obtaining the evidence giving rise to the inequitable conduct claim. Teva, thus, only recently became aware of these defenses—long after the time for amendment without leave had passed. Teva does not propose to amend its answer to add these newly discovered defenses and counterclaims for any bad faith or dilatory purpose—had Plaintiffs not withheld information about the inequitable conduct committed to obtain the patents-in-suit until the very end of fact discovery, Teva would have raised these issues sooner. Adding these defenses and

counterclaims would cause no prejudice to plaintiffs. All of the information related to Teva's new defenses and counterclaims of inequitable conduct is, and has been, in Plaintiffs' possession. Plaintiffs have been working with the witnesses Teva deposed, including the sole named inventors of each of the patents-in-suit, for several months. And they alone have controlled access to all information relating to the preparation and prosecution of the patents-in-suit. So Teva's inequitable conduct counterclaims and defenses can hardly be said to come as a surprise to Plaintiffs. Moreover, the parties have already agreed to extend fact discovery in this case. Finally, far from futile, the proposed amendment is based on settled Federal Circuit precedent.

Because leave to amend "shall be freely given," Fed. R. Civ. P. 15(a)—a "mandate" the Supreme Court has made clear is "to be heeded," *Foman v. Davis*, 371 U.S. 178, 182 (1962)—Teva respectfully submits that amendment is warranted here. A copy of Teva's proposed Amended Answer, Defenses, and Counterclaims—with new inequitable conduct defenses and counterclaims set forth in paragraphs 34 to 51, 55 to 65, 78 to 84, and 89 to 93—is attached as Exhibit A.

NATURE AND STAGE OF THE CASE

On April 6, 2005, Plaintiffs Smith Kline & French Laboratories, Ltd. and SmithKline Beecham Corp., d/b/a GlaxoSmithKline (collectively "GSK") filed this action alleging that Teva's filing of its Abbreviated New Drug Application ("ANDA") No. 77-460 with the United States Food & Drug Administration ("FDA") infringed GSK's '808 and '860 patents and that the manufacture, use, offering for sale, sale or importation into the United States of ropinirole hydrochloride tablets under Teva's ANDA would infringe those two patents. Compl. ¶¶ 19-30.

The '808 patent claims a class of compounds that includes 4-(2-di-n-propylaminoethyl)-2(3H)-indolone ("ropinirole") hydrochloride and compositions including

those compounds. The '860 patent addresses a method of treating Parkinson's Disease by administering an effective non-toxic amount of a class of compounds which includes ropinirole hydrochloride. GSK makes, markets, and sells certain ropinirole hydrochloride tablets under the trade name ReQuip.

Teva timely filed its Answer on April 26, 2005 denying infringement and asserting affirmative defenses of non-infringement and invalidity. Teva's Answer also included counterclaims seeking declaratory judgment that (1) the filing of Teva's ANDA did not infringe, and the manufacture, use, offering for sale, sale or importation into the United States of ropinirole hydrochloride tablets under Teva's ANDA will not infringe, any valid claim of either the '808 patent or '860 patent; and (2) the '808 patent and '860 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112 and 116 of Title 35 of the United States Code.

On August 8, 2005, this Court entered a stipulated Scheduling Order that set November 4, 2005 as the last date to file motions to amend pleadings. The Scheduling Order also set a date of May 31, 2006 to end fact discovery, and scheduled trial for five days beginning December 18, 2006. However, the parties continue to be engaged in discovery, which has been extended through June 30, 2006 by agreement of the parties.

Teva presently moves for leave to file an amended answer to Plaintiffs' complaint in order to add defenses and counterclaims asserting that Plaintiffs' patents-in-suit are unenforceable because they were procured by inequitable conduct. These new defenses and counterclaims are set forth with particularity paragraphs 34 to 51, 55 to 65, 78 to 84, and 89 to 93 of the amended answer attached as Exhibit A hereto.

SUMMARY OF ARGUMENT

Motion for leave to amend pleadings to add claims and defenses should be liberally granted, particularly where adding the claims and defenses would not unduly delay the case or prejudice the parties and the amendment is not sought for an improper purpose. Because inequitable conduct must be plead with specificity, Teva has only recently uncovered the facts necessary to plead these new defenses and counterclaims.

Teva's discovery efforts have revealed that the following grounds for finding that each of the patents-in-suit was inequitably obtained and, as a result, unenforceable. With respect to the '808 patent:

(1) the sole named inventor, Mr. Gallagher, filed a false declaration attesting that he was the sole inventor of the broad invention claimed therein;

(2) Mr. Gallagher's declaration improperly vouched for false statements in the '808 patent application to the effect that ropinirole and the other claimed compounds did not exhibit tachyphylaxis, unlike a prior art compound;

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(4) at least one individual who should have been named as a co-inventor of the '808 patent did not disclose to the PTO material prior art that was known to him.

Similarly, with respect to the '860 patent:

(1) the sole named inventor, Dr. Owen, filed a false declaration attesting that he was the sole inventor of the broad invention claimed therein, when in fact university researchers were the first to come up with a definite and permanent idea of the claimed invention; and

(2) Dr. Owen did not disclose a prior art reference he co-authored that contradicted statements in the '860 patent that mischaracterized the method of action of the prior art bromocriptine compound to distinguish it from what was known about the claimed ropinirole compound.

These facts were obtained in the course of deposing Plaintiffs' witnesses who were only made available within the last month of the fact discovery period.

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Based on this recently discovered information, Teva requests that it be permitted to amend its answer to raise defenses and counterclaims based on these instances of Plaintiffs' inequitable conduct.

STATEMENT OF FACTS

The Court's original deadline for amending pleadings elapsed more than six months before the close of fact discovery. Subsequent discovery by Teva has revealed facts showing that the '808 patent and '860 patent are invalid under 35 U.S.C. § 116 for failure to correctly join the individual(s) responsible for conceiving of the entire claimed invention(s). Because each of the named inventors for these patents deliberately submitted sworn declarations to the United States Patent & Trademark Office ("PTO") falsely attesting that they were the sole inventors of their respective patents, these facts also support a finding of inequitable conduct that would render each of the patents unenforceable. Moreover, in the course of obtaining this invalidity discovery, Teva also learned that the applicants committed other acts of inequitable conduct in obtaining the two patents-in-suit, rendering each patent unenforceable.

A. Recently Discovered Evidence Demonstrates That The '808 Patent Was Procured Through Inequitable Conduct.

First, as noted above, REDACTED

Gregory Gallagher is the sole named inventor of the '808 patent. (Exhibit B).

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This testimony contradicts Mr. Gallagher's sworn declaration, as submitted to the PTO, in which he claimed that he was the "original, first and sole inventor ... of the invention ... described and claimed in the attached specification" for the '860 patent. (*See* 12/6/82 Gallagher Decl., marked as Dep. Exhibit 44, and attached hereto as Exhibit E).

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Second, the '808 patent misstates that ropinirole was shown to "not cause tachyphylaxis in the [perfused hind limb] preparation as did its 7-hydroxy congener of the prior art" and improperly implies that this characteristic of ropinirole suggests that the remaining claimed compounds also "may not be subject to tachyphylaxis." (*See* Exhibit B, col. 4, ll. 48-52; col. 1, ll. 48-50.)

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Thus, Mr. Gallagher falsely vouched for the veracity of these statements with the intent to deceive the PTO and convince it to accept the assertions that ropinirole and the other claimed compounds had more selective activity and improved physiological characteristics from compounds known in the prior art.

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–Cannon, J.G., Demopoulos, B.J., Long, J.P., Flynn J.R. and Sharabi, F.M., "*Proposed Dopaminergic Pharmacophore of Lergotrile, Pergolide, and Related Ergot Alkaloid Derivatives*," J. Med. Chem. - Communications to the Editor, 1981, Vol. 24: 238-240 (1981) ("1981 Cannon article")(Exhibit H)–and had a duty to disclose material prior art references to the PTO. The 1981 Cannon article discloses a structurally similar compound to ropinirole and describes that compound as having both cardiovascular and central nervous system dopamine-agonist effects when administered in animal models. (*See* Exhibit H at page 238 (figure for compound 9).)

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In summary, through discovery

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Teva now has reason to believe the applicant engaged in inequitable conduct in prosecuting the '808 patent—specifically by (1) submitting Mr. Gallagher's false declaration of sole inventorship, (2) falsely vouching for the accuracy of the statement in the patent alleging that ropinirole lacked tachyphylaxis effects associated with the prior art, (3)

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and (4) failing to disclose material prior art.

B. Recently Discovered Evidence Demonstrates That The '860 Patent Was Procured Through Inequitable Conduct.

First, recent discovery has revealed the inequitable conduct associated with the naming of the inventor of the '860 patent. Like the '808 patent, the '860 patent names a single individual—Dr. David A. A. Owen—as the sole inventor of the entire invention(s) claimed therein. (Exhibit C) Claim 1 of the '860 patent identifies many compounds other than ropinirole or ropinirole hydrochloride for use in the claimed method of treating Parkinson's Disease. (*See* Exhibit C, col. 6, l. 67-col. 7, l. 4.)

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Second, the '860 patent specification falsely suggests that the anti-Parkinsonian activity of ropinirole and the other claimed compounds would not be understood by those of ordinary skill in the art unless it was also known that the claimed compounds acted on post-synaptic D_2 receptors, rather than pre-synaptic D_2 receptors. The '860 patent supports this suggestion by mischaracterizing the prior art bromocriptine compound, which was known as a treatment for Parkinson's disease, as a "post-synaptic dopamine agonist" in the brain and distinguishing the well-known pre-synaptic activity of the claimed compounds as cardiovascular agents to argue that those of ordinary skill in the art would not believe the claimed compounds could also be used to treat Parkinson's disease. (*See* Exhibit C at col. 1, ll. 36-39: "An alternative [prior art] form of therapy is to administer *post*-synaptic dopamine agonists, for example ergot alkaloids such as bromocriptine ....")

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Dr. Owen did not disclose this material prior art indicating the pre-synaptic activity of bromocriptine to the PTO, even though that article (Ex. I Dep. Ex. 56) was published in 1986—a year before the British patent application corresponding to the '860 patent was filed.

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In summary, through discovery

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Teva now has reason to believe the applicant engaged in inequitable conduct in submitting the false declaration of sole inventorship by Dr. Owen and in the intentional mischaracterization of the synaptic activity of the prior art compound bromocriptine involved information material to the patentability of the invention(s) claimed in the '860 patent and made with the intent to deceive the PTO and convince it to issue the '860 patent.

ARGUMENT

Rule 15(a) provides that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). The factors to consider in weighing a motion for leave to amend are well-settled: (1) whether the amendment has been unduly delayed; (2) whether the amendment is brought for some improper purpose; (3) whether the amendment would unfairly prejudice the non-moving party; and (4) whether the amendment is futile. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 487 (D. Del. 2003) (granting motion to assert inequitable conduct defense). Here, all four factors unequivocally support granting leave.

A. Teva's Proposed Amendment Is Timely.

Teva's amendment is timely because Teva could not have plead these inequitable conduct defenses and counterclaims earlier in the case. Inequitable conduct claims and defenses fall within the scope of Federal Rule of Civil Procedure 9(b), and therefore, must be pled with particularity. *See Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) ("[I]nequitable conduct, while a broader concept than fraud, must be pled with particularity."); *see also EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996). Teva's motion for leave comes shortly after Teva took key

depositions of REDACTED

To be clear, Teva first asked to depose these individuals on March 15, 2006 and took these depositions at the earliest dates offered by Plaintiffs, all of which came within the last month of the scheduled fact discovery period. Thus, while this Court's scheduling order anticipated that amendments would be submitted by November 4, 2005, Teva should be permitted to amend its answer now because it has sought leave to amend "soon after it was able to satisfy the pleading requirements" for an inequitable conduct defense. *Enzo*, 270 F. Supp. 2d at 490.

Moreover, Plaintiffs refused to produce certain documents central to Teva's inequitable conduct allegations until after the close of fact discovery—

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In light of Plaintiffs' considerable delay in presenting their witnesses for deposition and producing key documents, Teva has not unduly delayed bringing these inequitable conduct defenses and counterclaims. Moreover, as this Court has observed, a "party's delay in moving to amend a pleading generally is an insufficient ground to deny an amendment, unless that delay unduly prejudices an opposing party." *Hill v. Equitable Bank, N.A.*, 109 F.R.D. 109, 112 (D. Del. 1985). Here, there is no such prejudice to Plaintiffs. Teva promptly disclosed the basis for its inequitable conduct defenses and counterclaims in

supplemental interrogatory responses served June 9, 2006.[1] Plaintiffs' counsel was present at all of the depositions that Teva relies upon to support its inequitable conduct defenses and counterclaims. And to the extent Plaintiffs may argue that they need additional evidence to oppose Teva's inequitable conduct claims, they alone have access to that information.

B. Teva's Proposed Amendment Is Brought in Good Faith.

Teva's amendment is not brought for any improper purpose. As explained below in subsection D, Teva's amendment is entirely consistent with the law of inequitable conduct. Indeed, Teva's good faith in seeking leave to amend its answer, defenses, and counterclaims is demonstrated by the fact that it waited to obtain evidence, such that it could plead inequitable conduct with particularity, rather than making unfounded allegations and seeing what sticks. Were the Court to deny Teva leave to amend, now that evidence supporting an inequitable conduct claim has come to light, it would either encourage the widespread pleading of arguably unsubstantiated inequitable conduct claims or altogether preclude inequitable conduct defenses in many cases. This Court has previously concluded that "the Rule 9(b) 'pleading with particularity' requirement is implicated with regard to an inequitable conduct claim." *Enzo*, 270 F. Supp. 2d at 489. Thus it is "prudent" and "possibly required to confirm the factual allegations through discovery." *Id.* Having waited until discovery confirmed an inequitable conduct claim was available, Teva should not be penalized.

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C. Plaintiffs Will Not Be Unduly Prejudiced By Teva's Proposed Amendment.

Teva's amendment to add the proposed new inequitable conduct defenses and counterclaims will not unfairly prejudice Plaintiffs in conducting subsequent discovery or presenting a defense. As described above in subsection A, the timing of Teva's motion for leave and any subsequent amendment permitted by the Court would not prejudice GSK. Moreover, discovery on the additional defenses and counterclaims would cover the same or similar ground to GSK's claims and Teva's existing invalidity defenses and counterclaims. In any event, the evidence regarding Teva's inequitable conduct allegations *comes from GSK's own documents and witnesses*. As a result, Teva does not believe that the addition of Teva's inequitable conduct defenses and counterclaims will delay trial. To the extent Plaintiffs contend that they need additional discovery to oppose Teva's inequitable conduct allegations, Plaintiffs should be required to specify what additional discovery is needed and explain how that discovery was unrelated to Teva's existing invalidity defenses.

Moreover, to the extent plaintiffs have suffered any prejudice, it arises from their own dilatory tactics in waiting until the last month of fact discovery to offer all of their fact witnesses, including the two sole named inventors of the patents-in-suit and all of Plaintiffs' Rule 30(b)(6) witnesses. To the extent Teva's timing in asserting its inequitable conduct claims causes any prejudice to Plaintiffs, Teva is not to blame.

D. Teva's Proposed Amendment Is Not Futile.

Finally, Teva's amendment is far from futile. To establish that its proposed amendment is not futile, Teva need only show at this stage that its inequitable conduct allegations "state a claim upon which relief could be granted." *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Thus, this Court can only reject Teva's motion for leave to amend its answer

on futility grounds if the inequitable conduct counterclaims and defenses Teva seeks to add would not survive a Rule 12(b)(6) motion to dismiss. *See id.* at 122.

Patent applicants "are required to prosecute patent applications 'with candor, good faith, and honesty.'" *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). "A breach of this duty can take several forms: 'affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false information.'" *Id.* Inequitable conduct rendering the patent unenforceable may be found where such a breach "is coupled with an intent to deceive or mislead the PTO." *Id.* Here, the recently discovered evidence demonstrates that Teva may properly allege inequitable conduct.

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, Teva must prove that: (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. *See Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Information is deemed material if "there is a substantial likelihood that a reasonable examiner would have considered the material important in deciding whether to allow the application to issue as a patent." *See Elk Corp.*, 168 F.3d at 31. The recently discovered evidence described above now permits Teva to allege with particularity these elements of inequitable conduct with respect to the '808 and '860 patents.

Specifically, based on what it has learned through discovery, Teva can now allege, with respect to the '808 patent that: (1) Mr. Gallagher, the putative sole inventor, made a

false declaration of sole inventorship (Am. Answer (Ex. A) ¶¶ 35-43, 80); (2) the applicant(s), their representatives and/or others substantively involved in the prosecution of the applications that issued as the '808 patent falsely represented to the PTO that ropinirole, unlike the prior art, lacked tachyphylaxis effects (Am. Answer ¶¶ 44-46, 81); (3)

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and (4) the applicant(s), their representatives and/or others substantively involved in the prosecution of the applications that issued as the '808 patent failed to disclose material prior art (Am. Answer ¶¶ 48, 83).

Likewise, based on what it has learned in discovery concerning the '860 patent, Teva may now allege that: (1) Dr. Owen, the putative sole inventor, made a false declaration of sole inventorship (Am. Answer ¶¶ 56-61, 91); and (2) the applicant(s), their representatives and/or others substantively involved in the prosecution of the applications that issued as the '808 patent intentionally mischaracterized the method of action of a prior art compound used to treat Parkinson's disease in order to distinguish it from what was known in the art about ropinirole's method of action and withheld an article Dr. Owen co-authored that would have contradicted the patent's mischaracterization (Am. Answer ¶¶ 62, 92).

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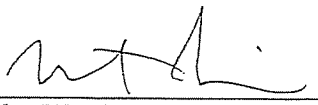
These allegations adequately support a claim for improper inventorship and inequitable conduct under the governing Federal Circuit case law. Inventorship deficiencies are plainly material. *See Perseptive Biosys., Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000). Indeed, the submission of any signed declaration with the intent that it be relied on by the examiner is inherently material. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1192-93 (Fed. Cir. 2006). Moreover, the submission of such declarations can, based on the circumstantial evidence, demonstrate an intent to deceive. *See id.* Similarly, mischaracterizations of the prior art or of the claimed compound have frequently been found material and the basis for a finding of inequitable conduct. *See, e.g., Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1371 (Fed. Cir. 2003) ("that the inventors misrepresented the prior art enzyme and its activity as compared to that of the claimed enzyme" was material for purposes of inequitable conduct finding); *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1360 (Fed. Cir. 2005) (inclusion in patent of "prophetic" example of method of making claimed invention deemed inequitable conduct in light of withheld evidence of failures using that method). And the Federal Circuit has also found material an applicants' false statements implying that a compound has been tested in humans. *Purdue Pharma LP v. Endo Pharms., Inc.*, 438 F.3d 1123, 1134 (Fed. Cir. 2006) (patentee's failure to disclose that claim of medical effects over a dosage range "was based on insight rather than experimental

data" was material for inequitable conduct determination). Accordingly, Teva's allegations are not futile and its motion should be granted.

CONCLUSION

For the foregoing reasons, Teva respectfully submits that its Motion to Amend its Answer, Defenses, and Counterclaims should be granted.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Monté T. Squire, Esquire, hereby certify that on July 6, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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